

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT
ASSOCIATION,

Plaintiff,

v.

NEW YORK CITY BOARD OF HEALTH, *ET AL.*,

Defendants.

No. 07 Civ. 5710 (RJH)

**REPLY MEMORANDUM IN SUPPORT OF
MOTION FOR PRELIMINARY INJUNCTION,
DECLARATORY RELIEF AND PARTIAL SUMMARY JUDGMENT**

ARNOLD & PORTER LLP

399 Park Avenue
New York, New York 10022
(212) 715-1000

*Counsel for Plaintiff, New York State
Restaurant Association*

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TABLE OF AUTHORITIES

<u>Cases</u>	<u>Page(s)</u>
<i>Bates v. Dow Agrosciences LLC</i> , 544 U.S. 431 (2005).....	16, 18
<i>Baxter Healthcare Corp. v. Denton</i> , 15 Cal. Rptr. 3d 430 (Cal. Ct. App. 2004).....	39
<i>Central Hudson Gas & Electric Corp. v. Public Service Commission of New York</i> , 447 U.S. 557 (1980).....	<i>passim</i>
<i>Chaplinsky v. New Hampshire</i> , 315 U.S. 568 (1942).....	37
<i>Chevron, U.S.A. v. Natural Resources Defense Council</i> , 467 U.S. 837 (1984).....	1, 20
<i>Cohen v. McDonald's Corp.</i> , 808 N.E.2d 1 (Ill. App. 1 Dist. 2004)	4
<i>Edenfield v. Fane</i> , 507 U.S. 761 (1993).....	28, 29
<i>Friedman v. Rogers</i> , 440 U.S. 1 (1979).....	34
<i>Goya De Puerto Rico v. Santiago</i> , 59 F. Supp. 2d 274 (D.P.R. 1999).....	16
<i>Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston</i> , 515 U.S. 557 (1995).....	23
<i>In re R.M.J.</i> , 455 U.S. 191 (1982).....	37
<i>International Dairy Foods Association v. Amestoy</i> , 92 F.3d 67 (2d Cir. 1996)	24, 27, 35
<i>Kordel v. United States</i> , 335 U.S. 345 (1948).....	21

	<i>Page(s)</i>
<i>Lorillard Tobacco v. Reilly</i> , 533 U.S. 525 (2001).....	31, 39
<i>Marcus v. FTC</i> , 354 F.2d 85 (2d Cir. 1965).....	39
<i>McConnell v. FEC</i> , 251 F. Supp. 2d 176 (D.D.C. 2003), <i>aff'd in part, rev'd in part</i> , 540 U.S. 93 (2003)	39
<i>National Cable & Telecommunications Association v. Brand X Internet Services</i> , 545 U.S. 967 (2005).....	20
<i>National Electrical Manufacturers Association v. Sorrell</i> , 272 F.3d 104 (2001).....	<i>passim</i>
<i>Paris Adult Theatre I v. Slaton</i> , 413 U.S. 49 (1973).....	37
<i>Pelman v. McDonald's Corp.</i> , 237 F. Supp. 2d 512 (S.D.N.Y. 2003).....	3, 4
<i>Public Citizen, Inc. v. Shalala</i> , 932 F. Supp. 13 (D.D.C. 1996)	2, 3, 20, 21
<i>Reyes v. McDonald's Corp.</i> , 2006 WL 3253579 (N.D. Ill. Nov. 6, 2006)	4, 18, 19, 21
<i>Riley v. National Federation of the Blind of North Carolina, Inc.</i> , 487 U.S. 781 (1988).....	22, 33
<i>Rubin v. Coors Brewing Co.</i> , 514 U.S. 476 (1995).....	38, 39
<i>United States v. Diapulse Manufacturing Corp. of America</i> , 269 F. Supp. 162 (D. Conn. 1967).....	21
<i>United States v. Haggar Apparel Co.</i> , 526 U.S. 380 (1999).....	9, 11

	<i>Page(s)</i>
<i>United States v. Mead Corp.,</i> 533 U.S. 218 (2001).....	9
<i>United States v. United Foods, Inc.,</i> 533 U.S. 404 (2001).....	<i>passim</i>
<i>Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.,</i> 425 U.S. 748 (1976).....	37
<i>West Virginia Board of Education v. Barnette,</i> 319 U.S. 624 (1943).....	27
<i>Wooley v. Maynard,</i> 430 U.S. 705 (1977).....	27
<i>Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio,</i> 471 U.S. 626 (1985).....	<i>passim</i>
<u>Statutes and Regulations</u>	
2 U.S.C. § 434	39
15 U.S.C. §§ 68 <i>et seq.</i>	38
15 U.S.C. § 78l.....	38
15 U.S.C. § 1333.....	39
21 U.S.C. § 321.....	20, 21
21 U.S.C. § 343.....	<i>passim</i>
21 U.S.C. § 343-1(a)(4)	1, 3
21 U.S.C. § 343-1(a)(5)	1, 2, 3, 4, 5, 15
21 U.S.C. § 343-1(b).....	17
27 U.S.C. § 205.....	39
33 U.S.C. § 1318.....	39
42 U.S.C. § 11023.....	39

Page(s)

Pub. L. No. 101-535, 106 Stat. 4501	2
Section 3(b)(1)(A).....	6, 7, 11, 19
21 C.F.R. § 100.2	17
21 C.F.R. § 101.9(c).....	14, 18
21 C.F.R. § 101.9(g)	18
21 C.F.R. § 101.9(j)	5
21 C.F.R. § 101.10	5, 15, 16, 19, 21
21 C.F.R. § 101.13	11
21 C.F.R. § 101.13(b)	9, 10, 11, 13
21 C.F.R. § 101.13(c).....	8
21 C.F.R. § 101.13(i)	9, 10, 11, 14
21 C.F.R. § 101.13(n)	8
21 C.F.R. § 101.45	21
21 C.F.R. § 101.54	5, 14
21 C.F.R. § 101.60	10, 11
21 C.F.R. § 202.1	38
29 C.F.R. § 1910.1200	39
Cal. Health & Safety Code § 25249.6.....	39
N.Y. Agric. & Mkts. Law § 214-h.....	38
N.Y. E.C.L. § 33-0707	39

Legislative and Administrative Materials

H.R. Rep. No. 101-538 (1990).....	3, 8
-----------------------------------	------

	<i>Page(s)</i>
56 Fed. Reg. 60421 (Nov. 27, 1991).....	8, 9
58 Fed. Reg. 2302 (Jan. 6, 1993)	11, 12, 13, 14, 22
58 Fed. Reg. 2462 (Jan. 6, 1993)	16, 17
58 Fed. Reg. 2478 (Jan. 6, 1993)	22
58 Fed. Reg. 33056 (Jun. 15, 1993).....	21, 22
61 Fed. Reg. 40320 (Aug. 2, 1996).....	3, 21
FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments,” <i>available at</i> http://www.cfsan.fda.gov/~frf/qatext2.html (last visited July 18, 2007).....	9, 14

Other Authorities

<i>Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity</i> , Final Report, May, 2006, <i>available at</i> http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf (last visited July 19, 2007)	<i>passim</i>
Johnny H. Killian, George A. Costello and Kenneth R. Thomas, <i>The Constitution of the United States of America: Analysis & Interpretation</i> (Sen. Doc. 108-17) (2002).....	37
Robert Post, <i>Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Association</i> in United Foods, Zauderer, and Abood, 40 Val. U. L. Rev. 555 (2006)	24

TABLE OF CONTENTS

	<i>Page</i>
I. THE NATIONAL LABELING AND EDUCATION ACT PREEMPTS REGULATION 81.50.....	1
A. The Statutory and Regulatory Scheme	2
B. A Statement By A Restaurant About The Amount Of Calories In Food Is A “Claim” that “Expressly Or By Implication Characterizes The Level Of Any Nutrient” Within the Meaning of Subsection (r).....	5
1. The Statute Is Unambiguous In Governing Express Claims of the Amount of Calories in Food	6
2. The FDA’s Regulations Are Unambiguous In Governing Express Claims of the Amount of Calories in Food— Including the Claim “100 Calories”.....	9
3. The City’s Argument Leads To Irrational Results.....	13
C. Regulation 81.50 Is “Not Identical To” 21 CFR § 101.10 And Thus Is Preempted.....	15
D. The NLEA Authorized the FDA to Promulgate 21 CFR § 101.10.....	18
E. Contrary to the City’s Argument, Restaurant Menu Boards Are Included Within the Statute’s Definition of “Labeling”	20
II. REGULATION 81.50 VIOLATES THE FIRST AMENDMENT RIGHTS OF PLAINTIFF’S MEMBERS	21
A. Regulation 81.50 Impermissibly Compels Speech	23
B. Regulation 81.50 Cannot Survive Review Under <i>Central Hudson</i>	27
1. Regulation 81.50 Does Not Directly Advance The City’s Asserted Interest In Curbing Obesity.....	28
2. Regulation 81.50’s Infringement On Speech Is More Extensive Than Necessary To Serve The City’s Asserted Interest.....	31
C. <i>Zauderer</i> And <i>Sorrell</i> Are Inapplicable.....	32
1. Regulation 81.50 Has Chilled Speech	33
2. Regulation 81.50 Does Not Prevent Unlawful Conduct.....	34
3. Regulation 81.50 Does Not Limit Itself to Factual, Non-Controversial Information.....	35

	<i>Page</i>
4. Regulation 81.50 Does Not Prevent Misleading Speech.....	36
D. The City's Parade of Horribles Is Not Real.....	38
CONCLUSION.....	40

I. THE NATIONAL LABELING AND EDUCATION ACT PREEMPTS REGULATION 81.50

The City and its *amici* begin their discussions of express preemption by discussing a provision that does not apply to the case and that Plaintiff has not claimed applies to this case—21 U.S.C. § 343-1(a)(4). When the City does discuss the applicable provision, section 343-1(a)(5), it argues that the provision does not apply here because the posting of calorie content by restaurants is not a nutrition content “claim” covered by regulations promulgated under section 343(r) and thus does not fall within subsection (r)’s corresponding preemption provision. According to the City and *amici*, posting calorie information is not a nutrition content “claim” because such posting does not “characterize” the level of the nutrient (*i.e.*, calories). At the same time, the City admits that posting the calorie content would be covered by section 343(r) if the restaurant used “descriptive words, such as ‘contains.’” Def. Br. 9 n.11. Under this reading of the statute, a restaurant that claimed on its menu that a certain food item “contains” 100 calories (when it in fact contained 500 calories) would be covered by section 343(r), and the restaurant would have misbranded its product under the NLEA. But, according to the City and its *amici*, the same restaurant could evade coverage of section 343(r) and the FDA’s regulations by removing the word “contains” and listing the same “100 calories” next to the name of the same food item. That is not what the statute and regulations say.

We respectfully urge the Court to reject these strained arguments. The statute requiring preemption is clear. Through its regulations (which warrant deference under *Chevron, U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837 (1984)), and its explanations of those regulations, the FDA has also made it clear that a statement such as

“100 calories” is a permissible “nutrient content claim” as long as it is not false or misleading.

A. The Statutory and Regulatory Scheme

As demonstrated in Plaintiff’s opening brief at pages 8 to 18, Regulation 81.50 is barred by the express preemption provision of the National Labeling and Education Act of 1990 (“NLEA”).¹ Subsection (r) imposes restrictions on the ability of “food purveyors,” including restaurants, to make affirmative nutrition and health claims about food.

See Public Citizen, Inc. v. Shalala, 932 F. Supp. 13, 15 (D.D.C. 1996). The statute’s express preemption provision provides that “no State . . . may directly or indirectly establish . . . any requirement respecting any claim of the type described in section 343(r)(1) of this title [*i.e.*, nutrition content claims] made in the label or labeling of food [that] is not identical to the requirement of section 343(r) of this title [except claims which are explicitly exempted by section 343(r) itself—claims about cholesterol, saturated fat, dietary fiber and nutrients that can cause disease].” 21 U.S.C. § 343-1(a)(5). The NLEA expressly completely preempts state law that differs in any way from the requirements under section 343(r). Congress delegated the implementation of the NLEA to the FDA, which promulgated final regulations for nutrition and health claims for restaurant foods. The regulations provide that the same definitional standards apply to restaurant foods as to other foods with respect to making a nutrition claim. However, the FDA’s regulations give restaurants flexibility in determining how they comply with

¹ The NLEA, Pub. L. No. 101-535, 106 Stat. 4501, added new subsections 403(q) and (r) and 403A to the Federal Food, Drug and Cosmetic Act (“FDCA”). Some of the relevant provisions of the NLEA are codified at 21 U.S.C. §§ 343(r) and 343-1(a)(5), and others are not codified, but are set out as a note following 21 U.S.C.A. § 343(r).

the nutrition labeling requirements in order to encourage restaurants voluntarily to provide nutrition information. *See* 61 Fed. Reg. 40320, 40320 (Aug. 2, 1996).

Thus, the relevant statutes for restaurants—and for evaluating Regulation 81.50, which seeks to require some restaurants to post calorie information on their menus and menu boards—are 21 U.S.C. §§ 343(r) and 343-1(a)(5). However, before analyzing those statutes, it is useful to address section 343(q) briefly.² Subsection (q) governs mandatory nutrition labels for packaged foods. Restaurants are completely exempt from compliance with subsection (q). 21 U.S.C. § 343(q)(5)(A) (“Subparagraphs (1), (2), (3), and (4) shall not apply to food—(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments”). Congress exempted restaurants from subsection (q) because “full labeling [was] impractical.” *See* H.R. Rep. No. 101-538 at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337. Subsection (q)’s preemption clause is 21 U.S.C. § 343-1(a)(4). Courts have held that subsection (q) does not preempt state law concerning restaurants because restaurants are exempt from subsection (q) and thus equally exempt from its preemption section, 21 U.S.C. § 343-1(a)(4), by the statute’s express terms. *See Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003); but see *Cohen v. McDonald’s Corp.*, 347 Ill. App. 3d 627, 808 N.E.2d 1 (Ill. App.

² The thrust of *amicus* Public Citizen’s brief is that restaurants are exempt under section 343(q), and therefore, state law governing them is not preempted. The argument has no relevance to this case because Plaintiff’s member restaurants are claiming preemption under sections 343(r) and 343-1(a)(5), not sections 343(q) and 343-1(a)(4). Unlike subsection (q), subsection (r) does not exempt restaurants. *See Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13, 15 (D.D.C. 1996). Public Citizen’s discussion (Br. 14-16) of the legislative history of subsection (q) should not distract the Court from the real issue in this case, which is the scope of subsection (r)’s preemption provision.

1 Dist. 2004) (state law claims preempted under § 343-1(a)(4)).³

In contrast to subsection (q), which requires nutrition information panels on packaged food, subsection (r) governs the much broader category of nutrition claims and health claims in all “labels and labeling” of food. And, in contrast to the complete exemption for restaurants in subsection (q), restaurant foods have only a limited exemption under subsection (r) for four items: cholesterol, saturated fat, dietary fiber and nutrients that can cause disease. *Compare* 21 U.S.C. § 343(q)(5)(A)(i) with § 343(r)(5)(B). Outside the four specified exemptions, restaurants are subject to subsection (r).

Subsection (r) provides that if a “claim is made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of food,” the claim must be in compliance with regulations promulgated by the FDA. 21 U.S.C. § 343(r)(1)(A), (r)(2)(A)(i). And because restaurants are subject to subsection (r), the corresponding preemption provision in section 343-1(a)(5) applies to restaurants and forbids state regulation that is “not identical to” FDA regulations, except for regulations governing cholesterol, saturated fat, dietary fiber and nutrients that can cause disease.

The FDA has exercised authority delegated by Congress in the NLEA to promulgate labeling requirements applicable to restaurants that disclose nutrition information, and has purposefully given restaurants wide flexibility in the manner in

³ Public Citizen criticizes Plaintiff for not citing *Pelman* in its opening brief, but *Pelman* addressed subsection (q) and subsection (q)’s preemption provision. In fact, the only case that addresses preemption under subsection (r)—the claim at issue here—is *Reyes v. McDonald’s Corporation*, 2006 WL 3253579 (N.D. Ill. Nov. 6, 2006). Plaintiff relied on *Reyes* in its opening brief, but the City and the *amici* ignore it. *See infra* pp. 18-19.

which they do it. 21 CFR § 101.10. Subsection (r) requires regulations governing any “claim” “made in the label or labeling of the food which expressly or by implication characterizes the level of any nutrient.” *See* 21 U.S.C. § 343(r)(2)(A)(i). The FDA’s regulations provide that, if a restaurant makes “a claim . . . which expressly or implicitly characterizes the level of any nutrient,” it must do so in accordance with FDA regulations (except of course the regulations that apply to the four exempt categories, irrelevant here). Consistent with this regime, the FDA’s regulations cover restaurants that make claims about their nutritional information:

The following foods are exempt from this section or are subject to special labeling requirements . . . (2) Food products which are: (i) served in restaurants, *provided*, that the food bears no nutrition claims or other nutrition information in any context on the label or in labeling or advertising. Claims or other nutrition information subject the food to the provisions of this section.

21 CFR § 101.9(j) (emphasis in original); *see* 21 CFR § 101.13(n) (“Nutrition labeling in accordance with § 101.9, § 101.10, or § 101.36, as applicable, shall be provided for any food for which a nutrient claim is made.”). Because restaurants that *do* make “claims” *are* “subject . . . to” the NLEA and FDA’s regulations, 21 U.S.C. § 343-1(a)(5) preempts inconsistent state law.

B. A Statement By A Restaurant About The Amount Of Calories In Food Is A “Claim” that “Expressly Or By Implication Characterizes The Level Of Any Nutrient” Within the Meaning of Subsection (r)

The City’s core argument (and that of *amicus* Public Citizen) is that a statement of a calorie amount—“100 calories”—is not a “claim” that “expressly or by implication characterizes the level of any nutrient” within the meaning of subsection (r) and regulations promulgated thereunder. Def. Br. 8-9; Pub. Cit. Br. 6-8, 16-25.

1. The Statute Is Unambiguous In Governing Express Claims of the Amount of Calories in Food

Evaluation of this contention must begin with the words of the statute. Section 343(r) declares food to be “misbranded” if it bears a “claim . . . made in the label or labeling of food which expressly or by implication . . . characterizes the level of any nutrient which is of the type required by paragraph (q)(1) or (q)(2) to be in the label or labeling of food,” unless “the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.” 21 U.S.C. §§ 343(r)(1)(A), (r)(2)(A)(i). Subsection (q)(1), incorporated for this special purpose by subsection (r)(1)(A), requires disclosure of “the total number of calories.” 21 U.S.C. § 343(q)(1)(C).

Subsection (r) thus covers any “claim” that “expressly characterizes” “the level of any nutrient” in the labeling of food, and includes “the total number of calories” as one such nutrient. If a statement “100 calories” does not “expressly characterize” the “total number of calories,” it is hard to know what would. The City and Public Citizen, however, argue that “characterizations” cannot be quantitative (“100 calories”), but can only be qualitative. The statute itself forecloses that argument, for two reasons in addition to the plain language of subsection (r)(1)(A) itself.

First, the NLEA contains a provision with a delegation of authority relevant here. (This provision is not codified in Title 21 but can be found in the Notes after 21 U.S.C.A. § 343(r).) Section 3(b)(1)(A)(iv) of the NLEA provides that the Secretary “shall issue proposed regulations to implement section 403(r) of the . . . Act [21 U.S.C. § 343(r)] . . . [and that] [s]uch regulations shall permit statements describing the *amount* and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(1)(A)(i) of such Act [21 U.S.C. § 343(r)(1)(A)(i)].” Nutrition

Labeling and Education Act of 1990, Pub. L. No. 101-535, § 3(b)(1)(A)(iv), 106 Stat. 4501 (set out in Historical and Statutory Notes after 21 U.S.C.A. § 343(r)) (emphasis added). Here, the NLEA itself is directing that the Secretary promulgate regulations *under subsection (r)* concerning the amount of nutrients. Thus, statements describing the “amount” of nutrients in food are covered by 21 U.S.C. § 343(r)(1)(A)(i). Surely a statement “100 calories” is a statement “describing the amount” of total calories.

Second, section 343(r)(1) provides that nutrition fact statements required by subsection (q) on food labels (including the total calories) are not claims subject to subsection (r) *when they are presented in the nutrition fact panel*. 21 U.S.C. § 343(r)(1)(B) (“A statement of the type required by paragraph (q) of this section that *appears as part* of the nutrition information required or permitted by such paragraph [(q)—that is, on nutrition fact panels] is not a claim which is subject to this paragraph [subsection (r)]....”) (emphasis added). Thus, if the statement 100 calories “appears as part” of the nutrition fact panel required by subsection (q), it is not a “claim” within the meaning of subsection (r)(1). By carving out statements that “appear as part” of the nutrition panel, the statute confirms that when the very same statements appear *elsewhere* on label or labeling—*i.e.*, in locations *not* required by subsection (q)—then they *do* constitute “claims.” The FDA’s regulations, promulgated after notice and comment, codify this understanding of the statute:

Information that is required or permitted by § 101.9 [mandatory nutrition labeling requirements for food] or § 101.36 [mandatory labeling requirements for dietary supplements], as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. **If such information is**

declared elsewhere in the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.

21 CFR § 101.13(c) (emphasis added); *accord* H.R. Rep. No. 101-538 at 19 (1990), 1990 U.S.C.C.A.N. at 3349 (“Section 403(r)(1) . . . removes the statements as to the amounts of nutrients required by section 403(q) from the disclosure and other requirements of section 403(r). However, section 403(r) would apply to any statement that is not required by section 403(q), *including a statement identical to that on the nutrition label which appears on the front panel of the product.*”) (emphasis added). The FDA explained the significance of this statutory provision as follows in its notice of final rulemaking (for the rule that became 21 CFR § 101.13(c) quoted above):

The act specifically excludes statements that appear as part of nutrition information from the coverage of section 403(r)(1) of the act. This exclusion was included in the 1990 amendments to make it clear that the information required on the nutrition label, and the optional statements that are permitted as part of nutrition labeling, are not claims under section 403(r)(1) of the act and are not subject to the disclosure requirements in section 403(r)(2) of the act. (Congressional Record H5841 (July 30, 1990)). However, the legislative history of this provision specifically states that *the identical information will be subject to the descriptor requirements [in §343(r)(2)(A)] if it is included in a statement in another portion of the label.* (Id.). Consequently, FDA is proposing in § 101.13(c) that information that is required or permitted by § 101.9 to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. Proposed § 101.13(c) also states, however, that *if such information is declared elsewhere on the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.*

56 Fed. Reg. 60421, 60424 (Nov. 27, 1991) (emphasis added).

2. The FDA's Regulations Are Unambiguous In Governing Express Claims of the Amount of Calories in Food—Including the Claim "100 Calories"

The FDA regulations implementing the NLEA provide that nutrient content claims may be expressed as numbers or values—in other words, that a quantitative statement is a “claim” that “expressly characterizes” “the level of any nutrient” in the labeling of food within the meaning of subsection (r). Those regulations, promulgated after a notice-and-comment process, are entitled to “controlling weight,” *see United States v. Haggar Apparel Co.*, 526 U.S. 380, 390, 392 (1999), and “are binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute.” *See United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (footnote omitted).

Most prominently, 21 C.F.R. § 101.13(c), discussed above, addresses information required to be printed in a nutrition facts panel, such as “total calories,” and states that “[i]f such information is declared elsewhere in the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.” 21 CFR § 101.13(c). *See also* FDA, Food Labeling: Questions and Answers, Volume II, “A Guide for Restaurants and Other Retail Establishments” (hereinafter “FDA Q&A Vol. II”), Question/Answer Number 76 (advising restaurants that providing nutritional information subjects the restaurant to the requirements of the NLEA) (available at <http://www.cfsan.fda.gov/~frf/qatext2.html> (last visited July 18, 2007)).

In addition, at least two provisions of the FDA regulations (21 CFR §§ 101.13(b)(1) and 101.13(i)(3)) explained in this and the next paragraph define “nutrient content claims” in terms of the *amount* of the nutrient value. To understand the

significance of these definitions, one must first appreciate that the regulations—like the NLEA itself—cover both “expressed” and “implied” nutrient content claims. An “implied” nutrient content claim—which is not involved in this case—is defined by reference to certain “descriptor” words such as “healthy,” *see* 21 CFR § 101.13(b)(2). And here is how the FDA defines “expressed” nutrient content claims which is what this case is about: “An expressed nutrient content claim is ***any direct statement about the level*** (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” 21 CFR § 101.13(b)(1) (emphasis added).

The regulations go on to set forth the requirements for both “expressed” and “implied” nutrient content claims and specifically for when a claim “may contain a *statement about the amount* or percentage of a nutrient.” 21 CFR § 101.13(i). An implied nutrient content claim is allowed if the statement meets certain definitional requirements contained in “Subpart D” [§ 101.13(i)(1)], or if it fails to meet the definitional requirements in Subpart D but the label contains a disclaimer [§ 101.13(i)(2)]. In contrast, an expressed nutrient content claim is allowed irrespective of Subpart D, so long as “[t]he statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., ‘100 calories’ or ‘5 grams of fat’), in which case no disclaimer is required.” 21 CFR § 101.13(i)(3) (emphasis added).⁴

⁴ According to the City and Public Citizen, 21 CFR § 101.60 excludes statements such as “100 calories” from the “defin[ition of] nutrient content claims for the calorie content of foods.” Pub. Cit. Br. 24; *see* Def. Br. 9 n.12. However, § 101.60 does not define “nutrient content claims.” That definition is quoted above. *See supra* pp. 9, 10 (quoting §§ 101.13(b)(1), 101.13(c)). Rather, § 101.60 is a component of “Subpart D,” which treats certain implied claims and which is limited by § 101.13(i). Under § 101.13(i), nutrient content claims are permitted if they comply with a relevant section within “Subpart D”

[Footnote continued on next page]

Thus, section 101.13 of the FDA's regulations provides specifically that total calories is a "claim" if it appears anywhere besides the nutrition facts panel, and that "100 calories" is a permissible expressed nutrient content claim—in the words of the statute, a "claim" that "expressly characterizes" "the level of any nutrient" in the labeling of food. This regulation is of "controlling weight." *See Haggar Apparel Co.*, 526 U.S. at 392.

In its final rulemaking statement adopting the regulations under the NLEA upon which we rely above, following the notice and comment period, the FDA specifically rejected the argument now urged by the City and *amicus* Public Citizen. The FDA had been asked to *exclude* statements about "simple factual information" from the definition of "nutrient content claim" on the theory that such a statement is not "a claim that 'characterizes' the level of any nutrient" within the meaning of the statute. But the FDA rejected that contention, embraced the view that a quantitative factual "statement" about the amount of a nutrient is a "claim" that "characterizes the level" of the nutrient within the meaning of the statute, and promulgated final and binding regulations to that effect.

And the FDA rejected this contention for some of the same reasons we have urged above:

One comment stated that the claims that are subject to the proposed regulations, which implement section 403(r)(1)(A) of the act [21 U.S.C. § 343(r)(1)(A)], are appropriately called "nutrient descriptors," not "nutrient content" claims as proposed by FDA. The comment pointed out that the statutory language of the 1990 amendments does not include the phrase "nutrient content" claim. It stated that the words in section 403(r)(1)(A) of the act refer

[Footnote continued from previous page]

(§ 101.13(i)(1)), or if they do not comply with "Subpart D" but contain a disclaimer (*id.* § 101.13(i)(2)), or if they do not comport with Subpart D but make no implied claim (*id.* § 101.13(i)(3)). Since "100 calories" falls under § 101.13(i)(3), in order to be permissible, it need not comport with § 101.60 or anything else in Subpart D, and § 101.60 simply does not shed any light on whether "100 calories" is or is not a "claim."

to a covered claim as a claim that "characterizes the level of any nutrient * * *." The comment's purpose in contrasting the wording of the proposal and that of the statute is to limit the applicability of the regulation to claims about the level of a nutrient and to exclude statements about amounts of nutrients. The comment stated that simple factual information about the nutrient content of a food, for which no characterizing claims are made, is explicitly excluded from regulation under section 403(r)(1)(A) of the act. It said that the last sentence in section 403(r)(1) of the act provides that a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving, or 10 percent of the U.S. Recommended Daily Allowance (U.S. RDA) for vitamin C, or 50 milligrams (mg) of sodium—is not a claim characterizing the level of the nutrient. The comment requested that to assure that the regulations for section 403(r)(1)(A) of the act claims are not misunderstood to extend to nutrient statements that do not "characterize the level of a nutrient," all references to "nutrient content" claims be redesignated to "nutrient descriptors" or "nutrient descriptor claims."

The agency advises that while it can agree that the terms "nutrient descriptor" and "nutrient descriptor claims" may be used to describe the claims subject to section 403(r)(1)(A) of the act and these regulations, it does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food.

The [distinction] the comment draws between "nutrient descriptors" and "nutrient content" claims is unpersuasive. In fact, one of the sponsors of the 1990 amendments in the Senate specifically used the term "nutrition content claim" to refer to claims covered under section 403(r)(1)(A) (136 Cong. Rec. S16608 (October 24, 1990)). Moreover, the statement in section 403(r)(1) of the act referred to by the comment as excluding from coverage statements of the type contained in nutrition labeling, in fact excludes "a statement of the type required by paragraph (q) that appears as part of the nutrition information required or permitted by such paragraph * * *." FDA stated in the general principles proposal (56 FR 60421 at 60424), that the legislative history of this provision specifically states that the identical information [i.e., the identical information that would be required in the nutrition fact panel required by subsection (q)] will be subject to the descriptor requirements if it is included in a statement in another portion of the label (136 Congressional Record H5841

(July 30, 1990)). . . Furthermore, section 3(b)(1)(A)(iv) of the 1990 amendments provides that the mandated regulations "shall permit statements describing the amount and percentage of nutrients in food which * * * are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act." Again, if statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.

58 Fed. Reg. 2302, 2303-04 (Jan. 6, 1993) (emphasis added).

3. The City's Argument Leads To Irrational Results

As they must, the City and *amicus* Public Citizen acknowledge that the statement "contains 100 calories," is a nutrient content claim, *see* 21 CFR § 101.13(b), but they argue that the statement "100 calories" is not a nutrient content claim. Def. Br. 9-10; Pub. Cit. Br. 19-25. Plainly the two phrases mean the same thing. True, one uses the word "contains" and the other does not; but, in the context of nutrition amounts, what else could the statement "100 calories" mean, but that the food contains 100 calories?

Amicus Public Citizen further contends that the fact that the word "contains" is defined in the regulations is what makes the phrase a nutrient content claim. Pub. Cit. Br. 20-22. This argument has several flaws. First, the word "calories" is also defined in the regulations. 21 CFR § 101.9(c)(1).⁵ Second, the "definition" of "contains" on which Public Citizen relies is in section 101.54 (Pub. Cit. Br. 21), which is a component of

⁵ "Calories, total," 'Total calories,' or 'Calories': A statement of the caloric content per serving, expressed to the nearest 5-calorie increment up to and including 50 calories, and 10-calorie increment above 50 calories, except that amounts less than 5 calories may be expressed as zero."

“Subpart D,” not applicable to the type of “expressed” claim here at issue, *see supra* note

4. *Compare* 21 CFR §§ 101.13(i)(1) & (2) (governing claims that “implicitly characterize” the food) *with* § 101.13(i)(3) (governing claims that do not “in any way implicitly characterize” the food).⁶ Also, the definition of “contains” cited by the City and *amicus* is irrelevant for calories, because the definition concerns nutrients *other* than calories, *see* 21 CFR § 101.54 (applying “contains” requirements to nutrients listed in 21 CFR §§ 101.9(c)(8)(iv) and (c)(9), neither of which lists calories).⁷

Finally, the City and the *amicus* offer no plausible explanation why the two phrases—“contains 100 calories” and “100 calories”—should be treated differently under the statute. If they were correct, a food purveyor would be misbranding its food under the regulations implementing section 343(r) for saying “contains 100 calories” when an item actually contained 300 calories, but would **not** be misbranding its food under those regulations for falsely saying “100 calories,” instead of 300 calories. Under the City’s

⁶ The City’s reference to 58 Fed. Reg. 2302, 2310 (“[T]he statement 100 calories or 5 grams of fat on the principal display panel of a food would be a simple statement of amount that, by itself, conveys no implied characterization of the level of the nutrient.”) is irrelevant because this case does not concern implied characterizations; it involves express characterizations. Def. Br. 9-10; Pub. Cit. Br. 21-22. Similarly, Public Citizen’s reliance on no-action letters concerning *implicit* claims concerning “trans fat” and other matters are not germane. The issue here is “expressed claims” not “implicit claims.” Pub. Cit. Br. 22-23. Finally, the City’s and Public Citizen’s reliance on the FDA September 2003 bulletin is unavailing because the excerpt they quote simply tracks the language of 21 CFR § 101.13(i), which, as discussed *supra* pp. 9-10, supports Plaintiff’s position. Def. Br. 10; Pub. Cit. Br. 8, 22.

⁷ In a publication explaining how the NLEA applies specifically to restaurants, the FDA has explained that when the word “contains” is used with an amount of a nutrient, the amount is the characterization of the nutrient level, not the word “contains.” *See* FDA Q&A Vol. II, No. 94 (“Furthermore, depending on the context in which it is used, the term ‘contains’ may itself be a nutrient content claim. A statement such as ‘contains fiber’ is a claim that a food is a ‘good source’ of fiber. (See attachment B). However, in a statement that includes a quantitative declaration, e.g., ‘contains 2 grams of fiber,’ the amount of fiber in the food is characterized by the quantitative declaration, ‘2 grams,’ and the term ‘contains’ is a simple verb, not a nutrient content claim.”) (emphasis added).

theory, a restaurant could move in or out of the federal regulatory regime by adding or deleting the word “contains” before it disclosed “100 calories.” The City does not explain how the two goals of the NLEA it identifies—“give consumers nutrition information about the products they are consuming and . . . prohibit misleading [nutrition] claims”—are met by making such a captious distinction. Def. Br. at 6.

C. Regulation 81.50 Is “Not Identical To” 21 CFR § 101.10 And Thus Is Preempted

The City acknowledges that if restaurants’ statements regarding calories are “claims” “of the type described in section 343(r)(1),” then § 343-1(a)(5) preempts state law requirements “not identical to” the requirements of subsection (r), including regulations promulgated thereunder. Def. Br. 15-16; Pub. Cit. Br. 16-17.

To avoid preemption, the City argues that 21 CFR § 101.10, which grants restaurants flexibility on the manner in which they may present nutrient content claims, and the City’s Regulation 81.50 are the same. That argument is wrong. The City’s theory is that Regulation 81.50 “does not mandate restaurants to do anything different from what they are permitted to do” under 21 CFR § 101.10. Def. Br. 15. But 21 CFR § 101.10 permits restaurants to provide nutrition information in whatever “reasonable means” they choose, so long as the claims otherwise comport with applicable federal regulations. Regulation 81.50 is not identical to 21 CFR § 101.10. The City’s regulation limits the choices of the restaurants, interferes with the flexibility granted to them by federal law, and commands them to present their claims in a specific way, whether they like it or not. Thus, Regulation 81.50 mandates that restaurants make a claim in a manner that is not required under 21 CFR § 101.10. Because the City’s regulatory requirement is

not identical to the requirements of 21 CFR § 101.10, the City's regulation is preempted.

See Goya de Puerto Rico, Inc. v. Santiago, 59 F. Supp. 2d 274, 280 (D.P.R. 1999)

(preempting state food labeling law mandating information where NLEA labeling regulations gave food manufacturers discretion).

In an attempt to avoid the plain meaning of "not identical to," the City says that Regulation 81.50 survives because the regulation is "not affirmatively different" from the requirements of 21 CFR § 101.10 and cites a passage from Volume 58 of the Federal Register. *See* Def. Br. 15 (citing 58 Fed. Reg. 2462, 2462). However the FDA was there using "affirmatively different" as another way of saying that preemption must be based on "substantive differences" between the local and federal regulations, not differences based on the mere use of different words. Thus, "affirmatively different" seems to require the same inquiry as "not identical to." *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (asking whether the two laws are "genuinely equivalent" and not different simply because they use different "phraseology") (emphasis in original). But even if "not identical to" did mean something other than "affirmatively different," the statutory language would govern.

In a footnote, the City argues that finding Regulation 81.50 preempted would mean that local governments would lose their "historic police power" "to regulate menus of restaurants within their border." Def. Br. 15 n.19. This assertion is meritless. Under the NLEA, local governments retain the authority to enforce FDA food labeling requirements. *See* 21 CFR § 100.2. The regulatory history cited by the City confirms that local governments may not do what the City is attempting to do here—to balkanize federal food labeling requirements. *See* 58 Fed. Reg. 2462, 2462 (noting that "one of the

goals of the [NLEA] is national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 states in a cost-effective manner.”) (citing to NLEA legislative history).⁸

The City and Public Citizen argue that the Court must interpret the NLEA in a way that gives meaning to Congressional intent as stated in both subsections (q) and (r). Def. Br. 10; Pub. Cit. Br. 24-25. Plaintiff’s reading does exactly that. And, contrary to the argument by the City and Public Citizen, Plaintiff’s reading preserves a role for the states. Where (as here) a claim is “of a type” covered by subsection (r) and regulations promulgated thereunder, the states’ rules are not displaced altogether. They are preempted only to the extent that they are “not identical to” federal requirements. (See also n.8.)

Thus, for example, ordinary state law would not be preempted as long as it imposed requirements “identical to” the requirements of the NLEA and implementing regulations. Consider, for example, a state tort action complaining that a restaurant had mis-stated the amount of calories posted in its nutrition labeling. As we have shown, such labeling must be in accordance with the FDA’s regulations. For example, federal regulations would require the restaurant to employ the FDA’s methodology for

⁸ Public Citizen argues that were Regulation 81.50 preempted, the role of local governments as “laboratories for experimentation” would be lost. Pub. Cit. Br. 12 n.8. Yet the NLEA provides a mechanism to allow for just this sort of experimentation. Under section 343-1(b), local governments may petition the FDA for an exemption from NLEA preemption. Section 343-1(b) balances local government’s desire to promulgate non-uniform local law with the goal of achieving “national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 states in a cost-effective manner.” 58 Fed. Reg. 2462, 2462 (citation omitted). Thus, the FDA is empowered to permit local non-uniform laws that do not “unduly burden interstate commerce” and meet “a particular need for information which need is not met by the requirements of” the NLEA. 21 U.S.C. § 343-1(b)(2), (3).

calculating calories. *See* 21 CFR § 101.10. Similarly, the level of the claimed caloric content would have been within 20% of the base. *See* 21 CFR § 101.9(g)(5). If the state tort action were premised on a claim that the restaurant violated standards of behavior “identical” to these federal requirements, then under the holding of *Reyes*, 2006 WL 3253579, at *7, the action would not be preempted. But if the tort action were based on standards of behavior “not identical to” the federal requirements, then the action would be preempted. *Reyes* is the only case we have found that decided the preemption issue presented here—a case not discussed by the City or its *amici*.

In *Reyes*, the court found plaintiffs’ state-law claims imposing nutrition labeling requirements different from those of the NLEA and implementing FDA regulations to be preempted. *Id.* at *1. Plaintiffs filed suit for misrepresentation after McDonald’s corrected the nutritional values of calories and fat published in its brochures and on its website. While McDonald’s was exempt from subsection (q) of the NLEA, the court stated, it had voluntarily provided the nutrient information at issue, thereby losing its exemption from the FDA’s regulations promulgated under subsection (r), but gaining protection from “not identical” state laws under the NLEA preemption provision applicable to subsection (r). *Id.* at *4. Applying the Supreme Court’s preemption analysis in *Bates v. Dow Agrosciences LLC*, the *Reyes* court concluded that Plaintiffs’ misrepresentation claims could proceed “only” to the extent that “[p]laintiffs seek to enforce . . . the requirements of the NLEA, and nothing further.” *Id.* at *6.

D. The NLEA Authorized the FDA to Promulgate 21 CFR § 101.10

The City contends (Def. Br. 14-15) that section 101.10 is *ultra vires* because the FDA’s authority was limited to “defining” the “terms” restaurants should use in making

their nutrition claims. That argument is without merit. Section 343(r)(2)(A)(i) does not purport to limit the Secretary's authority in promulgating regulations in the manner the City suggests.

In the NLEA, Congress delegated broad authority and instructions to issue regulations to implement subsection (r). Thus, subsection (r)(2)(A)(i) anticipates that the Secretary would issue regulations defining "terms." In addition, section 3(b) of the NLEA provides an expansive instruction that the Secretary "shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, [21 U.S.C. § 343(r)]" and that such regulations "(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act, [and] (iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i)." Pub. L. No. 101-535, § 3(b), 106 Stat. 4501. Surely in identifying "claims" described in subsection (r) that "comply with" the NLEA and in permitting "statements describing the amount...of nutrients in food" that are "not misleading" and that are "consistent with terms defined in [the NLEA]," the FDA was well within its statutory authority to specify the manner in which such claims and statements could be presented to consumers.

Other provisions of the NLEA confirm that Congress intended and expected that the FDA would promulgate regulations governing the manner in which nutrition information is presented to consumers. *See, e.g.,* § 343(r)(2)(A)(ii) (allowing the Secretary to make regulations permitting a statement about the absence of a nutrient if the Secretary finds it would assist consumers in maintaining healthy dietary practices); § 343(r)(7)(A)(ii) (allowing the Secretary to expedite effectiveness of proposed

regulations if necessary to allow actions on petitions that would provide for information necessary to “enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food.”). In addition, section 343(r)(2)(G)(iv) provides that even if the Secretary has not promulgated regulations under (r)(2), a claim of the type described in (r)(1)(A) may be made, provided the claim is “stated in a manner . . . so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of the total daily diet.” *See also* 21 U.S.C. § 343(r)(2)(G)(iv) (similar language concerning health claims).⁹

E. Contrary to the City’s Argument, Restaurant Menu Boards Are Included Within the Statute’s Definition of “Labeling”

It is well-established that menus and menu boards are food “labeling” under the NLEA and therefore are subject to requirements of the NLEA and accompanying FDA regulations. *See Shalala*, 932 F. Supp. at 16. “Labeling” is defined under the FDCA as “all labels and other written, printed or graphic matter . . . accompanying such article.” 21 U.S.C. § 321(m).¹⁰ The term “accompanying such article” is broadly construed, encompassing any item that “supplements or explains [the article] No physical attachment one to the other is necessary. It is the textual relationship that is significant.” *Kordel v. United States*, 335 U.S. 345, 350 (1948). Accordingly, “‘accompanying’ has

⁹ To the extent the Court deems the statute to be silent on the extent of the statutory delegation, such silence must be resolved *in favor* of agency authority to regulate. *See Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Services*, 545 U.S. 967, 980 (2005); *Chevron*, 467 U.S. at 842-48.

¹⁰ The NLEA amended the FDCA by adding sections 403(q) and (r) and 403A. Thus, the FDCA’s definition section, 21 U.S.C. § 321, applies to subsection (r).

been given a broad interpretation and comprises any materials which are intended to make claims or refer to a product, regardless of whether they accompanied the product in time or in presence, on in neither.” *United States v. Diapulse Mfg. Corp. of Am.*, 269 F. Supp. 162, 165 (D. Conn. 1967) (citations omitted).

The FDA interprets food “labeling” expansively to include menus. *See* 61 Fed. Reg. 40320 (“Thus, the FDA concludes that the menu exemption [the exemption of restaurant menus that the FDA originally adopted] is not consistent with the congressional intent in adopting the 1990 amendments, and that there is no basis for exempting menus from coverage of [the NLEA].”) Judge Friedman came to the same conclusion in *Shalala*, 932 F. Supp. at 16 (holding that menus are food labeling subject to NLEA). This treatment is consistent with other kinds of food “labeling” governed by the NLEA. Brochures and websites are food “labeling” subject to the NLEA. *See, e.g.*, *Reyes*, 2006 WL 3253579, at *4 (nutrition information on brochures and websites “labeling” subjecting McDonald’s to NLEA). In-restaurant signs, posters, brochures, notebooks and charts are labeling as well. 21 CFR § 101.10 (approving 21 CFR § 101.45 as a method of presenting nutrition information for restaurants). As the FDA has correctly noted, it is “virtually impossible to distinguish menus from the other types of restaurant labeling, such as signs, placards and other point of purchase information.” 58 Fed. Reg. 33056 (June 15, 1993) (citing 58 Fed. Reg. 2302, 2387 and 58 Fed. Reg. 2478, 2516 (Jan. 6, 1993)).

II. REGULATION 81.50 VIOLATES THE FIRST AMENDMENT RIGHTS OF PLAINTIFF’S MEMBERS

The parties have suggested three possible lines of relevant cases under which

Regulation 81.50 might be evaluated under the First Amendment:

1. If Regulation 81.50 is properly analyzed under the line of cases dealing with “compelled speech” culminating in *United States v. United Foods, Inc.*, 533 U.S. 404 (2001), the City and its *amici* effectively concede that Regulation 81.50 cannot survive scrutiny.
2. If the Regulation, instead, must be analyzed under the intermediate scrutiny ordinarily applied to commercial speech, *see Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York*, 447 U.S. 557 (1980), the City and *amici* do not concede the point, but they make no serious effort to defend the Regulation. *See* Def. Br. 26 n.21 (addressing *Central Hudson* in a footnote).
3. That is why the City and *amici* argue so vehemently that the case must be evaluated only under a line of cases assessing “disclosure requirements.” *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626 (1985); *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104 (2001). Regulation 81.50 would not survive even if it were so evaluated because there is a complete disconnect between an asserted interest in “disclosure” and what this Regulation actually says and does. In any event, neither *Zauderer* nor *Sorrell* should govern this case, for four reasons. *First*, unlike the state laws at issue in those cases, Regulation 81.50 is constitutionally suspect because it has actually chilled speech. *See Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781 (1988). *Second*, Regulation 81.50 is not a necessary element to further a regulatory regime that makes certain conduct unlawful. *Third*, Regulation 81.50 requires restaurants to convey a point of view not their own and with which they disagree. *Fourth*, Regulation 81.50 is not a means of preventing or correcting misleading speech through

the disclosure of otherwise hidden factual information.

A. Regulation 81.50 Impermissibly Compels Speech

Regulation 81.50 turns a proposal to enter into a transaction—"Bacon-Cheeseburger Deluxe, \$2.99"—into a message about the health effects of that transaction: "Bacon-Cheeseburger Deluxe, 1,000 cal., \$2.99." The First Amendment does not permit state laws that compel speakers to voice messages dictated by the government. *See Pl. Br. 20-21.* This is a "fundamental rule" of First Amendment protection: the government cannot usurp a speaker's "autonomy to choose the content of his own message." *Hurley v. Irish-American Gay, Lesbian and Bisexual Group of Boston*, 515 U.S. 557, 573 (1995). Free speech protections of the highest order forbid the government from conveying its own message out of the mouth of an unwilling speaker, even a commercial speaker. As the Supreme Court held in *United Foods*, First Amendment values are put at "serious risk" even by a law "compel[ling] a particular citizen, or a discrete group of citizens, to pay special subsidies for speech on the side that it favors[.]" 533 U.S. at 412. This is an *a fortiori* case: Regulation 81.50 requires Plaintiff's members to "utter the speech itself." *Id.* at 413.

Amici attempt to distinguish *United Foods* on the ground that Regulation 81.50 does not involve "association between or among" restaurants and does not "mandate assessments of monies for advertising[.]" Brief of Jennifer L. Pomeranz of the Rudd Center for Food Policy and Obesity *et al.* ("Pomeranz Br.") 16. These distinctions actually *highlight* the Regulation's incompatibility with free speech. Under Regulation 81.50, individual restaurants are themselves required to convey the City's message, with which they disagree. *See infra* pp. 24-27. In contrast, *United Foods* concerned the

indirect injury of forced contributions to a group advertisement. As the Court itself recognized in *United Foods*, forcing speech (as here) is *worse* than the injury in *United Foods*, where the plaintiff was “required simply to support speech by others, not to utter the speech itself.” 533 U.S. at 413. The Supreme Court struck down the assessment at issue in *United Foods* as incompatible with the First Amendment.¹¹

The City and *amici* also attempt to distinguish this case from *United Foods* on the theory that no “message” has been forced on the restaurants subject to Regulation 81.50. Def. Br. 21; Pomeranz Br. 14-15. The law, they argue, merely requires the posting of “factual information which [affected restaurants] have already chosen to publicly disclose elsewhere” and, as a result, has nothing to do with the expression of a particular viewpoint. *Id.* But how can the City seriously contend that no “message” is intended? Under the City’s Regulation, the menu board—the restaurants’ most important tool for communicating with its customers—will unmistakably say to customers that if you want to buy this hamburger, you must consider the health aspects of the purchase and that in doing so the single fact to consider is the calorie count. *Cf. Int’l Dairy Foods Ass’n v. Amestoy*, 92 F.3d 67, 71-72 (2d Cir. 1996) (plaintiffs opposed law requiring labeling disclosure of rBST growth hormone in milk on the ground that “it compel[led] them ‘to convey a message regarding the *significance* of rBST use that is expressly contrary to

¹¹ One of Defendants’ *amici* contends, in an article, that *United Foods* is a “seriously misguided” case, “a mistake of the first magnitude,” and “in serious tension with *Zauderer*.” Robert C. Post, *Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Associations* in *United Foods*, *Zauderer*, and *Abood*, 40 Val. U. L. Rev. 555, 557, 575-7 (2006). That view may have animated *amici*’s advice to this Court. Nonetheless, the Supreme Court has not withdrawn from *United Foods* or from the way it limited *Zauderer* in *United Foods*. *See infra* p. 37. It is the law of the land.

their views'') (emphasis added; internal quotations omitted).

The City's own submissions in this case demonstrate that conveying the City's health message is, in fact, the entire purpose of the Regulation. In recounting the history of the provision, Commissioner Frieden explained that "although consideration was given to requiring that more of the available nutritional information be posted, a *choice was made to focus on calorie information[.]*" Frieden Decl. ¶ 8 (emphasis added). The Regulation requires the posting of only caloric content, thereby conveying to consumers a message concerning the singular importance of calories in nutritional decisionmaking.

Plaintiff's members disagree with Dr. Frieden's opinion. To take just one example, Ms. Haugen of Burger King Corporation explains:

BKC strongly disagrees with New York City's regulation which requires it to isolate and post calorie information on menu boards in its restaurants. As most nutritionists know, overemphasis on any one nutrient such as calories can interfere with consumers obtaining a healthy, varied diet. Rather, BKC believes that nutrition information must be provided within the broader context of what it means to have a healthy diet, with an emphasis on consumers acquiring an energy balance while moderating intake of nutrients such as sodium, fats, trans fats and cholesterol....

While calories are important, we disagree with the message that the New York regulation requires us to communicate to our customers. Limiting the information on menu boards to a single nutrient as a guideline to the healthfulness of a particular food is misleading and can cause consumers to make the wrong food choice for themselves....

Requiring BKC to publish calorie count of foods alone and in isolation on the menu boards will undermine our carefully developed program to communicate nutrition information to our customers.... Customers will attribute to BKC the message that calories are the most important nutrient and that a single calorie number is all they need to know. While this may be the City's desired message, it is not the message that BKC wants to convey or with which it agrees....

We do not agree with the message [Regulation 81.50] will force us to send to our customers. We believe it will undermine the nutritional message that we have carefully developed and chosen to send to our customers.

Haugen Decl. ¶¶ 14-18; *accord* DeMuth Decl. ¶¶ 14, 18; Liewen Decl. ¶¶ 4, 8;

Richardson Decl. ¶¶ 5; LeClair Decl. ¶ 5.

The City does not challenge the *bona fides* of these opinions or the good faith in which they are held. In view of this uncontested testimony, we do not understand how the City can legitimately argue that a menu board complying with Regulation 81.50 conveys no message at all. Regulation 81.50 compels restaurants to convey the City's message to the detriment of their own lawful opinions, desires and views.

The City and *amici* implicitly acknowledge the content-based nature of Regulation 81.50 by arguing that Plaintiff's members could try to counter the City's message by "post[ing] additional information and even a *disclaimer* if they so choose." Def. Br. 21 (emphasis added); Pomeranz Br. 14 ("If restaurants have the point of view that additional nutritional information is important for consumers to receive at the point of purchase, Health Code § 81.50 leaves them free to communicate this *viewpoint* and to provide whatever *additional data* they wish to their customers.") (emphasis added). In so arguing, the City and their *amici* ignore the practical burden imposed by the remedy they propose. As evidenced by the City's various illustrations of "compliant" menu boards, even integrating calorie information *alone* results in cramped, cluttered, and confused menu boards. *See, e.g.*, Frieden Decl. ¶ 65. "Curing" the Regulation's burden by adding complete nutritional information to menu boards—in the typeface and size compelled by Regulation 81.50—would be both a practical impossibility and a further, substantial impediment to restaurants' communication with their customers.

Moreover, the City's "disclaimer" suggestion belies a fundamental misperception of the protection afforded by the First Amendment. It would not have cured the constitutional violation in *Wooley v. Maynard*, 430 U.S. 705 (1977), for the plaintiff to add an "I'm a pacifist" bumper sticker as a "disclaimer" to the "Live Free or Die" motto on his license plate. It would not have cured the violation in *West Virginia Board of Education v. Barnette*, 319 U.S. 624 (1943), for the plaintiff to conclude, following his pledge of allegiance, with a "disclaimer" of "I don't actually believe this." And it would not have cured the violation in *United Foods*, 533 U.S. at 411-13, for the plaintiff to have taken out its own branded advertisements, nor in *International Dairy*, 92 F.3d at 71-72, for the plaintiff to have added a disclaimer to its milk labeling contending that rBST is perfectly safe. Simply put, the City's offer of "disclaimers" and "additional information" does not cure the constitutional violation; and in fact it highlights the message-based nature of the Regulation.

B. Regulation 81.50 Cannot Survive Review Under *Central Hudson*

Even if Regulation 81.50 did not fail as "compelled speech," it would fail under the test for commercial speech enunciated in *Central Hudson*. Under the standard set out in *Central Hudson*, governmental burdens on commercial speech are subject to a four-part inquiry asking: (1) whether the expression concerns lawful activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the challenged law directly advances the asserted interest; and (4) whether the challenged law is not more extensive than is necessary to serve the asserted interest. 447 U.S. at 566. The City does not allege that the menus or menu boards of those restaurants subject to Regulation 81.50 are misleading, much less that they concern unlawful activity. *See* Def.

Br. 26 n.21 (stating, in the context of *Central Hudson*, that “[t]here is no dispute as to the first two prongs”).¹² For its part, Plaintiff has acknowledged that the City’s asserted interest—protecting the public health—is a substantial one. The parties diverge, however, on *Central Hudson*’s other tests.

1. Regulation 81.50 Does Not Directly Advance The City’s Asserted Interest In Curbing Obesity

To survive scrutiny under *Central Hudson*, the City must prove that Regulation 81.50 advances the government’s asserted, substantial interest in a “direct and material way.” *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). This burden cannot be met by “speculation or conjecture”: the constitutional interests at stake require the government to “demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Id.* at 770-71. “Without this requirement, a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.” *Id.* at 771.

While documenting the ills of obesity, *see, e.g.*, Frieden Decl. ¶¶ 3-4, 9-22, the City provides only speculation and conjecture with regard to how the particular Regulation at issue would be effective in reducing obesity, relying on leaps of faith. The City’s reliance on speculation is unsurprising. First, as previously argued, the studies cited by the Department in promulgating its Regulation merely note the “potential” benefits of providing consumers with nutritional information. *See* Pl. Br. 26-27. The City does not and cannot argue that these studies prove that its Regulation “will in fact”

¹² The City’s concession that restaurants subject to Regulation 81.50 have not engaged in misleading speech or speech that concerns unlawful activity is equally significant under *Zauderer*, discussed *infra* pp. 35-37.

alleviate the harms of obesity “to a material degree.” *See Edenfeld*, 507 U.S. at 771.

Of particular interest here, Dr. Frieden’s extensive declaration devotes only two paragraphs to the effectiveness of the Regulation. Frieden Decl. ¶¶ 49-50. These paragraphs are filled with words that bespeak hypotheses, not conclusions based on evidence—“suggest,” “supposing,” “assume,” “likely.” *Id.* Even if the Regulation had no effect on consumer food choices, “it is likely to increase the number of lower-calorie...offerings these facilities provide.” *Id.* ¶ 50. This is conjecture upon conjecture; it is not based on any evidence. That is why Dr. Frieden himself concludes only that Regulation 81.50 has a “*potential* for public health impact.” *Id.* ¶ 49.

This defense of the Regulation’s effectiveness glosses over a great number of unanswered questions. The Keystone Forum Final Report (to which Dr. Frieden and *amici* look for support) explains:

There is a clear need for more research regarding how the provision of nutrition information, claims (such as “low calorie”), and symbols influence consumer preference and choice for away-from-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers’ responses to the provision of nutrition information and claims for away-from-home foods.

Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity, Final Report, at 83-84 (May 2006). The *Final Report* then suggested many “research questions” that needed answering, including “What type of information should be provided?.... How and where should information be provided, given the goals for providing such information? At point of sale, before sale, after sale for future purchases, etc.? Via menu board, brochure, table tent, poster, kiosk, etc.? If the information is

accessed, how is it used? Under what circumstances is current behavior influenced and under what circumstances is future behavior influenced? For example, if consumers consume an extra 100 calories at lunch, will they eat a lighter dinner?.... Is information on the caloric content of food items more likely to be used by the consumer when presented alone or when embedded in general nutrition content information?" *Id.*

All these questions are unanswered, not only by the City, but by the state-of-the-art research available. As the Keystone Forum Final Report put it,

Better and more timely information is needed regarding: the choices consumers are making regarding foodservice venues and foods, the values and motivations driving those choices, the factors that motivate changes in behaviors and attitudes, the potential value of nutrition information and other specific interventions, and the best ways to promote changes in products or menus that are relevant to weight management. . . .

Evidence regarding how and why consumers use nutrition information is limited. Outstanding questions include how consumers process and use such information, what measurable contribution the information can make to the goal of managing weight gain and obesity, where the point of decision-making is for away-from-home-foods consumers, and what effect information may have on consumer choice, eating behavior, and store revenue. Likewise lacking are data with regard to whether one format or another alters the rate of consumer usage of the information.

Id. at 46, 69; *see id.* at 22 ("The research base on obesity is incomplete and imperfect regarding some aspects of the problem, such as the potential effectiveness of specific interventions aimed at assisting consumers with managing their energy intake."); *id.* at 67 (listing as a "Basic Research Need" information on "What information, if any, regarding the nutritional composition of menu items prompts consumers to take action and choose items to manage weight?").

Dr. David Allison, whose declaration is submitted with this Memorandum, has done a review of the literature and of the specific articles upon which the City has previously relied. *See* Allison Decl. 17-18. Based on that review, he has concluded that it is possible to conjecture that Regulation 81.50 would be effective in meeting its goals, or that it would be ineffective, or that it would be positively harmful. *Id.* 24.

None of this is to say that speculation and conjecture are irrelevant to public policy. Although the kind of speculation and conjecture involved here might be sufficient to support certain government initiatives—for example, providing educational literature to city residents, or teaching good health practices in schools, or encouraging restaurants voluntarily to provide customers with certain information—it is insufficient to support a coercive governmental program burdening the First Amendment rights of those regulated. That is the core meaning of the third prong of *Central Hudson*.

2. Regulation 81.50's Infringement On Speech Is More Extensive Than Necessary To Serve The City's Asserted Interest

Even when a governmental burden on speech is effective to a material degree, it must still employ a means “narrowly tailored to achieve the desired objective.” *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 556 (2001) (internal quotations omitted). In this case, there are many alternatives for providing customers with caloric information in restaurants that would not so heavily burden restaurants’ First Amendment rights by co-opting their most important communication tool and using it to convey a message with which they disagree. These alternatives include signs directing consumers to comprehensive nutritional information, posters with complete nutritional information, food wrappers with such information, counter-mats with such information, stanchions

and flip-charts with such information, and prominently displayed brochures. *See* Horn Decl. ¶ 2-4; Colón Decl. ¶ 8-9; *Keystone Forum Final Report* App. J at pp. 128-33 (listing alternatives including websites, server-delivered information, second menus, health-oriented menu sections, health-related symbols for menus, tray liner information, packaging information, reference books, posters, handouts, brochures). Signs directing consumers to nutritional information elsewhere in a restaurant could be placed prominently on or near menu boards. Moreover, the City clearly anticipates customers making repeated visits to those restaurants subject to the ordinance; so any caloric information reviewed even after the time of purchase would inform the patron during later visits. Regulation 81.50, however, bars alternatives that do not “display[] calorie information at least as prominently as calorie information would otherwise be displayed using the format proscribed by section 81.50(b)(1).” Colón Decl. Ex. D. The City does not even attempt to defend this failure at narrow tailoring.

C. Zauderer And Sorrell Are Inapplicable

The City and its *amici* devote their briefs to the contention that Regulation 81.50 is merely a “disclosure requirement” subject to “reasonableness” review under Supreme Court’s decision in *Zauderer* and the Second Circuit’s decision in *Sorrell*.

The City relies most heavily on *Zauderer*. There, the State required that contingency-fee lawyers disclose to unsophisticated contingency-fee clients that they might have to pay litigation costs if their claims proved unsuccessful. 471 U.S. at 650. The Court explained that “an advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the *State’s interest in preventing deception of consumers.*” 471 U.S. at 651 (emphasis added).

In *Sorrell*, the Second Circuit applied *Zauderer* and upheld a statute that barred the dumping of products containing mercury and, to effect that ban, required sellers to “inform the purchaser or consumer that mercury [was] present in the item and that the item [could] not be disposed of or placed in a waste stream destined for disposal until the mercury is removed and reused, recycled, or otherwise managed to ensure that it does not become part of solid waste or wastewater.” 272 F.3d at 107 n.1.

Zauderer and *Sorrell* are inapplicable here, for at least four reasons. *First*, Regulation 81.50 is not a disclosure requirement at all; because it does not apply to those who choose not to disclose, it has actually chilled protected speech. *Second*, the Regulation is not an adjunct to a broader regulatory regime that makes certain conduct unlawful, as in *Sorrell*. *Third*, Regulation 81.50 bears on controversial speech and for that reason cannot be analogized to the “purely factual” and “non-controversial” disclosure at issue in *Sorrell*. *Fourth*, the Regulation cannot be justified as reasonably related to the prevention of consumer deception—the touchstone of *Zauderer* as limited by *United Foods*.

1. Regulation 81.50 Has Chilled Speech

Regulation 81.50, in purpose and in effect, does not actually advance the disclosure of any new information at all. To the contrary, the record is uncontested that Regulation 81.50 has actually *chilled* disclosure. *See* Frieden Decl. ¶ 36; Burnett Decl. ¶ 4; Richardson Decl. ¶ 4. This actual chilling of lawful and indeed desirable speech is powerful evidence that the City has gone too far: “unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.” *Zauderer*, 471 U.S. at 651; *see Riley*, 487 U.S. at 794.

The City and its *amici* ask this Court to turn a blind eye to the uncontested

evidence that speech has in fact been chilled by Regulation 81.50; their theory is that, in general, commercial speech is “less likely than other forms of speech to be inhibited by proper regulation.” *See Friedman v. Rogers*, 440 U.S. 1, 10 (1979); Def. Br. 27; Pomeranz Br. 18. But given the durability of commercial speech, the evidence of actual chilling stands as powerful testament to the City’s overreaching here.

The Regulation has driven some restaurants to withhold the caloric content of their food from consumers. Moreover, the Regulation creates a powerful incentive now for restaurants that do not provide nutritional information to their customers to continue to remain silent for all time.¹³ The “marketplace of ideas” has been impoverished, rather than enhanced. *See Sorrell*, 272 F.3d at 114 (“disclosure furthers, rather than hinders, the First Amendment goal of the discovery of truth and contributes to the efficiency of the ‘marketplace of ideas’”). By infringing certain restaurants’ First Amendment rights, in other words, Regulation 81.50 effectively deprives consumers of information. *Zauderer* and *Sorrell* do not support such a provision.

2. Regulation 81.50 Does Not Prevent Unlawful Conduct

Regulation 81.50, unlike the law at issue in *Sorrell*, is not an adjunct necessary to implement a law that makes certain activity unlawful. In *Sorrell*, Vermont had made unlawful the dumping of mercury-containing products together with ordinary waste. It would have been virtually meaningless to pass such a law without also providing

¹³ In arguing that Regulation 81.50 cannot chill speech because the provision applies to all restaurants that did not withdraw their nutrition disclosures before March 1, 2007, *see Pomeranz Br. 18, amici* overlook the fact that, at some point in time (past or future), each restaurant faced or will face a choice of “opting out,” whether by withdrawing information before March 1, 2007 (*see* Frieden Decl. ¶ 36), or simply by choosing to remain silent now and in the future.

consumers with information about which products were subject to this prohibition—information that was not otherwise known to them. Regulation 81.50 serves no analogous law-enforcement purpose. The distinction between laws mandating speech further to the context of a broad regulatory regime and those that do not was discussed at length in *United Foods*, 533 U.S. at 412-13.

3. Regulation 81.50 Does Not Limit Itself to Factual, Non-Controversial Information

Regulation 81.50 goes well beyond the documentation of uncontroversial information. Because *Zauderer* and its progeny focus on the prevention of deception, their reach is limited to “purely factual and uncontroversial information[.]” *See Zauderer*, 471 U.S. at 651. *Sorrell*, by its own terms, applies only to laws requiring disclosure of accurate, factual non-controversial information. As the Circuit acknowledged, a regulation “[r]equiring actors in the marketplace to espouse particular opinions would likely raise issues not [there] presented[.]” 272 F.3d at 114 nn.4-5.

Plaintiff’s members vigorously dispute the City’s point of view that informed nutritional decisions can be made by considering calories out of the context of other nutritional values. *See supra* pp. 25-26. The Keystone Forum, on which the City and *amici* rely, observed that “[t]he range of views on this topic, outlined here, may help the reader to understand the complexity of the issue and the diverse and sometimes strong views that the topic generates among stakeholders.” *Keystone Forum Final Report* at 70.

The Second Circuit’s decision in *International Dairy Foods Association* is instructive. There, the Court enjoined the enforcement of a Vermont law that required dairy producers to label all products made with rBST, a growth hormone used to treat

dairy cattle. 92 F.3d at 69, 73. While the disclosure mandated by the statute was undoubtedly true as a factual matter, the law required milk producers “to convey a message regarding the significance of rBST use that [was] expressly contrary to their views.” *Id.* at 71 (internal quotations omitted). The Second Circuit applied *Central Hudson* and struck down the law. *Id.* at 74.¹⁴

4. Regulation 81.50 Does Not Prevent Misleading Speech

Regulation 81.50 does not purport to protect against potentially misleading speech. The City justifies the regulation as a way of achieving the state’s interest in reducing obesity. *See* Def. Br. 26 n.21.¹⁵ Plaintiff certainly agrees that public health is a substantial governmental interest. That is not in dispute. But to further *this* interest, as opposed to the interest in preventing deceptive commercial speech, the City may not burden speech without meeting the standards of *United Foods* and *Central Hudson*.

The City and *amici* claim that *Zauderer* opened the door to any and all state disclosure requirements “regardless of why the disclosure of uncontroverted facts [was] being mandated.” Def. Br. 19. But *Zauderer*’s identification of the “State’s interest in preventing deception of consumers,” 471 U.S. at 651, was not merely the fortuitous byproduct of the particular facts that happened to be before the Court. It was, rather, the necessary consequence of earlier decisions defining the boundary between misleading speech, which is not protected at all by the First Amendment, and commercial speech,

¹⁴ *United Foods* had not yet been decided when the Second Circuit decided *International Dairy*, so the court applied *Central Hudson*.

¹⁵ While the City and its *amici* suggest in passing that Regulation 81.50 addresses consumers’ “inaccurate perceptions” regarding the caloric content of food, Def. Br. 26; Pomeranz Br. 11, they cannot seriously maintain that “Hamburger, \$1.99” is deceptive.

which is protected.

The Court has long held that certain forms of “speech” are simply beyond the ambit of First Amendment protection. *See Paris Adult Theatre I v. Slaton*, 413 U.S. 49 (1973) (obscenity); *Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942) (fighting words). Misleading commercial speech falls within this category. *See In re R.M.J.*, 455 U.S. 191, 203 (1982) (“Misleading advertising may be prohibited entirely.”); *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (same). As one scholarly text explains, “certain commercial speech is not entitled to protection; the informational function of advertising is the First Amendment’s concern and if an advertisement does not accurately inform the public about lawful activity, it can be suppressed.” Johnny H. Killian, George A. Costello and Kenneth R. Thomas, *The Constitution of the United States of America: Analysis & Interpretation*, at 1180 (Sen. Doc. 108-17) (2002).

Thus, in developing First Amendment protection for commercial speech, the Supreme Court has expressly linked the validity of so-called “disclosure” requirements to their ability to protect against potentially misleading speech. As the Court explained in *Virginia State Board*, the state may regulate potentially “deceptive or misleading” commercial speech by “requir[ing] that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.” 425 U.S. at 771 n.24. Similarly, the Court explained in *R.M.J.*, the state “may not place an absolute prohibition on certain types of *potentially* misleading information … if the information also may be presented in a way that is not deceptive Although the potential for deception and confusion is particularly strong in

the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.” 455 U.S. at 203 (emphasis added); *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 494 (1995) (Stevens, J., concurring) (“[A]ny description of commercial speech that is intended to identify the category of speech entitled to less First Amendment protection should relate to the reasons for permitting broader regulation: namely, commercial speech’s potential to mislead.”).

The *Zauderer* case fits comfortably within this line of cases. It holds that a “disclosure requirement” affecting commercial transactions must protect against potentially misleading information. It has been so limited by the Supreme Court in *United Foods*, which rejected application of *Zauderer* to the law there at issue on the ground that there was “no suggestion” in *United Foods* “that the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make voluntary advertisements nonmisleading for consumers.” 533 U.S. at 416. We recognize that *Sorrell* rejected the limitation of *Zauderer* set forth in *United Foods*, but it is unclear how this aspect of *Sorrell* can be reconciled with *United Foods*. In any event, *Sorrell* is distinguishable for the reasons discussed *supra* pp. 33-36.

D. The City’s Parade of Horribles Is Not Real

The City contends that every disclosure statute or regulation on the books will be put in jeopardy if Plaintiff prevails. But each requirement the City and *amici* cite is either directed toward preventing deception or unlawfulness in commercial transactions,¹⁶ is

¹⁶ See, e.g., 15 U.S.C. § 78l (registration requirements for securities, including anti-fraud disclosures); 21 U.S.C. § 343 (preventing misbranding in food); 21 C.F.R. § 202.1 (regulating drug advertisements to protect consumers from misleading advertisements); N.Y. Agric. & Mkts. Law § 214-h (requiring retail stores to disclose unit and total price information); 15 U.S.C. §§ 68 *et seq.* (requiring labeling of wool products’ actual wool content, so as to

[Footnote continued on next page]

plainly subject to review under *Central Hudson* or even stricter scrutiny,¹⁷ is necessary to prevent otherwise unlawful activity,¹⁸ or does not concern commercial speech at all.¹⁹ Significantly, neither the City nor its *amici* point to a single statute or rule that they believe would fail under the reading of *United Foods* or *Central Hudson* urged by Plaintiff but would be saved by their reading of *Zauderer*. Their parade of horribles is just a way to avoid focusing on what the Regulation at issue here actually says and what it actually does.

[Footnote continued from previous page]

protect consumers against concealment of substitutes for wool in products claimed to be made wholly or partially of wool, *see Marcus v. FTC*, 354 F.2d 85 (2d Cir. 1965)).

¹⁷ 2 U.S.C. § 434 (political committee receipts and disbursements, *see McConnell v. FEC*, 251 F. Supp. 2d 176 (D.D.C. 2003), *aff'd in part, rev'd in part*, 540 U.S. 93 (2003)); 15 U.S.C. § 1333 (cigarette labeling, *see Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525); 27 U.S.C. § 205 (labeling of alcoholic beverages, *see Rubin v. Coors*, 514 U.S. 476); Cal. Health & Safety Code § 25249.6 (warnings of persons who will be intentionally exposed to carcinogens, *see Baxter Healthcare Corp. v. Denton*, 15 Cal. Rptr. 3d 430, 449 n.5 (Cal. Ct. App. 2004)).

¹⁸ *See Sorrell*, 272 F.3d at 107 n.1.

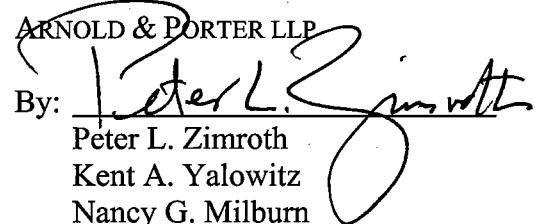
¹⁹ *See, e.g.*, 33 U.S.C. § 1318 (preparation and filing of point source pollution discharge reports); 42 U.S.C. § 11023 (preparation and filing toxic chemical release reports); 29 C.F.R. § 1910.1200 (employer notifications of workplace chemical hazards); N.Y. E.C.L. § 33-0707 (submission of pesticide formulas to state commissioner).

CONCLUSION

The Court should enter an order: (1) granting declaratory and summary judgment in favor of Plaintiff on its preemption claim, and (2) granting a preliminary injunction against enforcement of Regulation 81.50 pending a final adjudication of the merits.

Dated: July 20, 2007
New York, New York

Respectfully submitted,

ARNOLD & PORTER LLP
By: 
Peter L. Zimroth
Kent A. Yalowitz
Nancy G. Milburn
Brandon Cowart

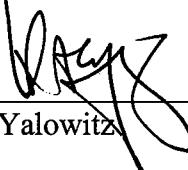
399 Park Avenue
New York, New York 10022
(212) 715-1000

*Counsel for Plaintiff, New York State
Restaurant Association*

CERTIFICATE OF SERVICE

I, Kent A. Yalowitz, the undersigned attorney at law duly admitted to practice in the State of New York, respectfully show that on the 20th day of July, 2007, the annexed **REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION, DECLARATORY RELIEF AND PARTIAL SUMMARY JUDGMENT** was served by hand delivery upon:

Mark W. Muschenheim
Assistant Corporation Counsel
Corporation Counsel of the City of New York
100 Church Street
New York, New York 10007



Kent A. Yalowitz